

**PATENT COOPERATION TREATY**

31 OCT 2004

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

**PCT**

To:

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ETATS-UNIS D'AMERIQUE

**NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

(PCT Rule 71.1)

*Registered letter.*

Date of mailing  
(day/month/year)

19/03/2004

Applicant's or agent's file reference <b>1662/58676</b>		IMPORTANT NOTIFICATION	
International application No. <b>PCT/US03/13002</b>	International filing date (day/month/year) <b>23/04/2003</b>	Priority date (day/month/year) <b>23/04/2002</b>	
Applicant <b>TEVA PHARMACEUTICAL INDUSTRIES LTD. et al.</b>			

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

**4. REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  <b>KEMLE S Y G</b> Tel. (+49-89) 2399 2828	 Europäisches Patentamt Office européen des brevets
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## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

(Rationalised Report according to the Notice of the President of the EPO published in the OJ11/2001)

Applicant's or agent's file reference <b>1662/58676</b>	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/US03/13002</b>	International filing date ( <i>day/month/year</i> ) <b>23/04/2003</b>	Priority date ( <i>day/month/year</i> ) <b>23/04/2002</b>	
International Patent Classification (IPC) or national classification and IPC <b>A61K9/14</b>			
Applicant <b>TEVA PHARMACEUTICAL INDUSTRIES LTD. et al.</b>			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 2 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

I  Basis of the report

II  Priority

III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

IV  Lack of unity of invention

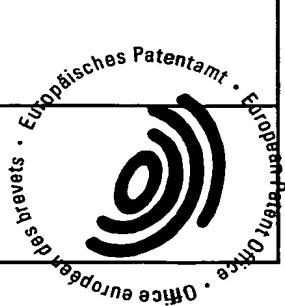
V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI  Certain documents cited

VII  Certain defects in the international application

VIII  Certain observations on the international application

Date of submission of the demand <b>10/11/2003</b>	Date of completion of this report <b>16/03/2004</b>
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**I. Basis of the report**

The basis of this international preliminary examination is the application as originally filed.

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been the subject of the international preliminary examination in respect of the claims which have not been searched (Article 17(2)(a) or (3) and Rule 66.1(e) PCT; see also international search report).

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out:

In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims, which have been the subject of an international search report, does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claim references).